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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/673,872	12/04/2000	Tony Wai-Chiu So	C7979U	5826
20529	7590	06/11/2007		
NATH & ASSOCIATES 112 South West Street Alexandria, VA 22314			EXAMINER LANDAU, SHARMILA GOLLAMUDI	
			ART UNIT	PAPER NUMBER
			1616	
			MAIL DATE	DELIVERY MODE
			06/11/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/673,872

Applicant(s)

WAI-CHIU SO ET AL.

Examiner

Sharmila Gollamudi Landau

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 March 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6, 8, 10-16, 19-21, 23, 24 and 26-138 is/are pending in the application.
- 4a) Of the above claim(s) 10-11, 34-35, 45-111, 115-117, 129-130, and 134 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) See Continuation Sheet is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims rejected are 1-4, 6, 8, 12-16, 19-21, 23-24, 26-33, 36-44, 112-114, 119-128, 131-133, and 135-138.

DETAILED ACTION

Receipt of Response to the Restriction Requirement filed 3/19/07, the Terminal Disclaimers filed 10/30/06, and the Amendments/Remarks filed 12/6/06 is acknowledged.

Election/Restrictions

Applicant's election with traverse of an aerosol, mousse, or foam product (note spray is included); alcohol as the penetrating agent, and glycerol as the co-solvent the reply filed on 3/19/07 is acknowledged. The traversal is on the ground(s) that the species do not impose a serious burden on the examiner. This is not found persuasive because: As acknowledged by applicant, a serious burden is shown when the inventions can be classified separately. The examiner points out that the product forms are separately classified. For instance, an aerosol is classified in 424/47 or whereas gels are classified in 514/944. Thus, the different products are classified separately. With regard to the co-solvents, as set forth in the species requirement, applicant is claiming different types of co-solvents, i.e. aromatic, glycols, and glycerol. Similarly, applicant is claiming numerous penetrating agents, i.e. bile acid (classified 424/528), esters (for instance, carboxylic acid esters classified in 560/1), amines (classified in 564/1), etc. which constitutes a burdensome search. It is unclear if applicant is claiming that the species are obvious variants. If applicant is arguing that they are obvious variants, then the examiner must state this clearly for the record, and upon doing so, the examiner will withdraw the species requirement.

Accordingly, claims 1-4, 6, 8, 12-16, 19-21, 23-24, 26-33, 36-44, 112-114, 119-128, 131-133, and 135-138 are directed to the elected species. Claims 10-11, 34-35, 45-111, 115-117, 129-130, and 134 are withdrawn as being directed to a non-elected species.

The requirement is still deemed proper and is therefore made FINAL.

Withdrawn Rejections

1) The rejection of claims 1-3, 6, 8-9, 12-17, 19, 21, and 23 under 35 U.S.C. 103(a) as being unpatentable over Bazzano (5183817) in view of WO 97/12602 or Yu et al (EP0273202) respectively is withdrawn in light of the amendment to the claim language (consisting essentially of) excluding retinoic acid.

2) The terminal disclaimer filed on 10/30/06 has been reviewed and is accepted. The terminal disclaimer has been recorded and the rejection over claims 1-4, 6, 8-9, 12-18, 21, 23 is withdrawn.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-3, 6, 8, 12, 13, 15-16, 19-21, 23-24, 26-29, 112-114, 118-119, 121-128, 131-132, 135-138 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 88/01863 to Peck et al in view of WO 97/12602 or Yu et al (EP0273202) respectively.

Peck teaches a quick breaking foam to treat baldness comprising either (a) 1-5% minoxidil; (b) 10-50% propylene glycol; (c) 30-75% alcohol; (d) 0.5-10% emulsifier and/or surfactant; (e) 0.1-5% hydroxypropyl methylcellulose; and (f) 10-50% water wherein the composition is actuated with a propellant. See page 2. Peck teaches the minoxidil may be selected from any known analog. Peck teaches skin penetrants including alcohol such as dodecanol and oleyl alcohol. See page 5. Peck teaches various surfactants in the composition including Tween 80 (polysorbate) and Span 60 to improve the stability of the composition. See page 6, lines 20-25. Peck teaches the use of minoxidil or a salt thereof. See page 5, lines 25-30.

Peck does not teach the instant acid salt.

WO teaches a topical composition for minoxidil and teaches minoxidil is not soluble in water, acetone, and ethyl acetate and although the alcohol based solutions of minoxidil have only some penetration. See page 2. WO teaches modifying the solubility of the active in an aqueous solution by making it more hydrophilic without changing the active agent's therapeutic

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properties. The active agent that is more hydrophilic, has improved penetration through the hair follicle. WO teaches modifying by reacting it with an hydroxy organic acid such as lactic acid. See page 3 and 4.

Yu et al teach additives such as hydroxy acids enhance the therapeutic effects of pharmaceutical and cosmetic actives in topical treatments. See page 2. The pharmaceutical or cosmetic active is utilized generally in the amount of 0.01-40% and the hydroxyl acid is used in the amount of 0.01-99%. See page 6. Yu teaches the use of 3% lactic acid with minoxidil to help the minoxidil dissolve in the solution and enhance penetration and the efficacy of minoxidil on hair growth. The pH of the solution is 4.7. See example 3.

It is would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Peck and WO and utilize the instant minoxidil acid salt. One would have been motivated to do so since WO teaches this addition to yield a hydrophilic compound, allows for better penetration into the hair follicles. Alternatively, it would have been obvious to one of ordinary skill in the art at the time the invention was made combine the teaching of Peck and Yu et al and utilize the instant acid. One would be motivated to do so Yu teaches adding lactic acid dissolves minoxidil providing better penetration of minoxidil. Therefore, a skilled artisan would have been motivated to add an acid to form a minoxidil acid salt for enhanced penetration of minoxidil into the hair follicle.

With regard to the instantly claimed ratio of ethanol to water, Peck sets forth a general range of components wherein the alcohol is utilized in an amount of 30-75% and water from 10-50%, thus it is within the skill of an artisan to look at the guidance provided by Peck and manipulate the concentrations (ratio) of water and ethanol depending on the concentration of the other components. It should be noted that generally difference in concentrations do not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such as concentration is critical. See *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Claims 14, 30-33, 36-44, 133 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 88/01863 to Peck et al in view of WO 97/12602 or Yu et al (EP0273202) respectively in further view of Uchikawa et al (5,156,836).

The teachings of Peck, Yu, and WO '602 have been set forth above.

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Peck does not teach the elected glycerol co-solvent or the use of an antioxidant.

Uchikawa teaches a hair revitalizing composition that may comprise minoxidil.

Uchikawa teaches conventional excipients used to formulate hair-revitalizing compositions include polyhydric alcohols such as glycerine and propylene glycol, antioxidants, etc. see column 4, lines 5-30.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of the above references and substitute the exemplified propylene glycol with the instantly claimed glycerol and arrive at the instant invention. One would have been motivated to do so since Uchikawa teaches both propylene glycol and glycerol are polyhydric alcohols conventionally used in the art. Therefore, a skilled artisan would have expected similar results absent unexpected results by using any conventional polyhydric alcohol known in the art in the composition. Further, it would have been obvious for a skilled artisan to further utilize a conventional excipient such as an antioxidant as taught by Uchikawa to prevent oxidation.

Claims 1-4, 6, 8, 12-13, 15-16, 20-21, 23-24, 26-31, 36-37, 39-44, 112-113, 118-128, 131-132, 135-136, 138 are rejected under 35 U.S.C. 103(a) as being unpatentable over Di Schiena (4866067) in view of Yu et al (EP0273202).

Di Schiena discloses minoxidil (0.1-10%, ex: 5%) combined with oxyniactic acid for topical treatment of alopecia. The reference discloses that minoxidil is insoluble in water and the salt form of minoxidil is soluble in a water-based composition. Therefore, an acid makes it remarkably soluble in water without loading the composition with glycols. Di Schiena discloses a foam composition containing the instant active, water, a lower alcohol, cetyl alcohol (penetration agent), propellant, laureth-4, and propylene glycol (9%) in a foam composition (note examples). The foam composition also contains cetyl alcohol and a surfactant. Di Schiena teaches methanol, ethanol, or isopropanol as suitable solvents (col. 2, lines 17-20 and examples. Further, the reference exemplifies a lotion containing the active without the use of a glycol, instant amount of water, ethanol, and active (example b). The examples teach a variety of water to lower alcohol ratios. Di Schiena teaches the use of antioxidants in the compositions.

Di Schiena does not teach the use of lactic or acetic acid.

Yu et al teach additives such as hydroxy acids enhance the therapeutic effects of pharmaceutical and cosmetic actives in topical treatments. See page 2. The pharmaceutical or cosmetic active is utilized generally in the amount of 0.01-40% and the hydroxyl acid is used in the amount of 0.01-99%. See page 6. Yu teaches the use of 3% lactic acid with minoxidil to help the minoxidil dissolve in the solution and enhance penetration and the efficacy of minoxidil on hair growth. The pH of the solution is 4.7. See example 3.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Di Schiena and Yu et al and add a hydroxyl acid such as lactic acid to the composition. One would have been motivated to do so since Yu teaches adding lactic acid dissolves minoxidil providing better penetration of minoxidil. Therefore, a skilled artisan would have been motivated to add an acid to form a minoxidil acid salt for enhanced penetration of minoxidil into the hair follicle. The use of a conventional excipient in the aerosol formulation is obvious since Di Schiena teaches the use of an antioxidant in the other formulations.

With regard to the claimed ratio, it would have been obvious to one of ordinary skill in the art at the time the invention was made to look to manipulate the parameters set forth in Di Schiena. One would have been motivated to do so as part of routine experimentation to yield the best possible results. Differences in concentration do not extend patentability to subject matter encompassed in the prior art unless there is evidence-indicating criticality.

Response to Amendment

Applicant argues that the claim language excludes oxyniacic acid. However, this argument is not persuasive since the claims are directed to "minoxidil or a pharmaceutically acceptable salt thereof". Di Schiena teaches reacting oxyniacic acid and minoxidil to form the compound of formula I, i.e. a minoxidil salt, which reads on a pharmaceutically acceptable salt of minoxidil.

The Declaration under 37 CFR 1.132 filed 5/22/06 is insufficient to overcome the rejection of claims based upon Di Schiena in view of WO 97/12602 because:

Although the examiner notes applicant's asserted unexpected property that the instant composition is homogenous whereas Di Schiena is only homogenous after being shaken, the examiner notes the claims are not commensurate in scope. For instance, applicant compared a

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specific “inventive” composition with specific components in specific weight percents and ratio with the prior art. Thus, the unexpected property of homogeneity is due to the components in the inventive composition and the specific ratio used in the Rule 132 declaration. Thus, the claims must be commensurate in scope.

Claims 1-4, 6, 8, 15-16, 19-21, 23-24, 26-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 07-048230 in view of WO 97/12602 or Yu et al (EP0273202) respectively in further view of Caldini et al (4,272,516).

JP ‘230 teaches a hair tonic with hair restoring properties comprising 0.1-10g minoxidil, 30-70g ethanol and water. See abstract.

JP does not specifically teach adding an acid or a cosolvent.

WO teaches a topical composition for minoxidil and teaches minoxidil is not soluble in water, acetone, ethyl acetate and although the alcohol based solutions of minoxidil have only some penetration. See page 2. WO teaches modifying the solubility of the active in an aqueous solution by making it more hydrophilic without changing the active agent’s therapeutic properties. The active agent that is more hydrophilic, has improved penetration through the hair follicle. WO teaches modifying by the pH reacting it with a hydroxy organic acid such as lactic acid. See page 3 and 4.

Yu et al teach additives such as hydroxy acids enhance the therapeutic effects of pharmaceutical and cosmetic actives in topical treatments. See page 2. The pharmaceutical or cosmetic active is utilized generally in the amount of 0.01-40% and the hydroxyl acid is used in the amount of 0.01-99%. See page 6. Yu teaches the use of 3% lactic acid with minoxidil to help the minoxidil dissolve in the solution and enhance penetration and the efficacy of minoxidil on hair growth. The pH of the solution is 4.7. See example 3.

Caldini et al teach a process for improving transcutaneous and transfollicular absorption of cosmetic compositions in the amount of 5-33.33%. See abstract. Caldini teaches benzyl alcohol has the ability of facilitating the absorption of the other components through the skin and its associated organs. See column 1, lines 10-20. The cosmetic compositions include a lotion for reactivating the hair, a reactivating jelly, a tonic milk, and a reactivating cream. See column 4, lines 40-45. Caldini teaches a reactivating lotion that comprises comprising a solvent system of 4% propylene glycol, 12% benzyl alcohol, 31.5% water, and 47.5% ethanol. See example 1.

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It is would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of JP and WO and utilize the instant minoxidil acid salt. One would have been motivated to do so since WO teaches this addition to yield a hydrophilic compound, allows for better penetration into the hair follicles. Alternatively, it would have been obvious to one of ordinary skill in the art at the time the invention was made combine the teaching of JP and Yu et al and utilize the instant acid. One would be motivated to do so Yu teaches adding lactic acid dissolves minoxidil providing better penetration of minoxidil. Therefore, a skilled artisan would have been motivated to add an acid for enhanced penetration of minoxidil into the hair follicle.

It would have been obvious at the time the invention was made to combine the teachings of the above references and utilize benzyl alcohol in the solvent system. One would have been motivated to do so since Caldini et al teach the use benzyl alcohol in an amount of 5-33.33% improves transcutaneous and transfollicular absorption of active agents, especially hair reactivating composition. Thus one would expect an additive effect of increasing penetration of the composition by adding benzyl alcohol in JP's composition. Note that the hair tonic reads on the elected species "spray" since the composition is capable of being sprayed.

With regard to the instantly claimed ratio of ethanol to water, Peck sets forth a general range of components wherein the alcohol is utilized in an amount of 30-70% and water to balance, thus it is within the skill of an artisan to look at the guidance provided by Peck and manipulate the concentrations (ratio) of water and ethanol depending on the concentration of the other components. It should be noted that generally difference in concentrations do not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such as concentration is critical. See *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Claims 1-4, 6, 8, 12-13, 15-16, 19-21, 23-24, 26-29, 112, 118-128, 131-132, 135-138 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 97/03638 to Navarro et al in view of WO 97/12602 to Weiner et al.

Navarro teaches the solvent system comprising the combination of ethanol or isopropyl alcohol and propylene glycol or polyethylene glycol solubilize minoxidil but the significant amount of propylene glycol makes the hair greasy and shiny. See page 2 of translation. Navarro

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teaches using cyclodextrin to reduce the amount of solvent required to solubilize minoxidil. See page 3 of the translation. Navarro teaches a hair care composition containing 0.1-7% minoxidil, 0.1-5% cyclodextrin, 0.5-15% minoxidil solvent (propylene glycol), 30-50% monoalcohol (ethanol or isopropanol), and water. Note abstract and examples.

Navarro does not teach the use of lactic or acetic acid.

Weiner teaches a topical composition for minoxidil. WO discloses that making materials more hydrophilic, improves penetration through the hair follicle. Weiner teaches that a number of different modifications may be made to the minoxidil. One such modification is provided by reacting minoxidil with an organic acid such as lactic acid. The minoxidil may also be converted to a salt by reacting it with a cyclodextrin. See page 3. Weiner states that the use of a minoxidil acid salt addition provides substantial penetration and cyclodextrin salt addition is the “next best”. See page 7. Weiner teaches encapsulation of minoxidil increase penetration of the active across the skin.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Navarro et al and Weiner et al and substitute Navarro's cyclodextrin with the instant acid to convert minoxidil into a salt. One would be motivated to do so since Weiner teaches that by converting minoxidil to a hydrophilic compound, it penetrates the skin penetrate. More specifically, Weiner teaches the conversion of minoxidil into a salt form by reacting it with an organic acid such as instant lactic acid or with cyclodextrin and notes that although both provide penetration of minoxidil, the acid salt addition has a better effect than the cyclodextrin salt addition. Therefore, one would have been motivated to use an acid salt addition to convert minoxidil into a hydrophilic compound rather than Navarro's cyclodextrin since Weiner teaches the acid salt addition has better penetration into the skin. With regard to the pH recited in the dependent claims, it is the examiner's position that the combination of Navarro and Weiner would yield a pH since the lactic acid would render a pH in the acidic range. The examiner cites Yu et al (EP '202) to support this position wherein lactic acid and minoxidil yield a composition with a range of 4.6.

With regard to the instantly claimed ratio, Navarro sets forth a general range of components wherein a monoalcohol is utilized in an amount of 30-50% and water to balance, thus it is within the skill of an artisan to look at the guidance provided by Navarro and

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manipulate the concentrations (ratio) of water and ethanol depending on the concentration of the other components. It should be noted that generally difference in concentrations do not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such as concentration is critical. See *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

With regard to claim 4, the lower limit of approximately 7.5% is considered obvious over Navarro's teaching that the minoxidil may be in the amount of 7%. A skilled artisan would have been motivated to manipulate the concentration of active, i.e. increase the amount of minoxidil, in the composition depending on the desired "strength" of the composition.

With regard to the penetration enhancer, the examiner points out that Weiner's liposome reads on "penetration agent". Therefore, a skilled artisan would have been further motivated to utilize a liposome such as taught by Weiner to increase penetration of the active across the skin.

Note that the hair tonic reads on the elected species "spray" since the composition is capable of being sprayed.

Response to Arguments

Applicant argues that the instant claim language excludes Weiner's lipid vehicle and cyclodextrin.

Applicant's arguments filed 10/30/06 have been fully considered but they are not persuasive. Firstly, the examiner notes that Weiner indicates that an encapsulated lactic salt of minoxidil has greater penetration than unencapsulated form. However, the examiner points out that Weiner teaches modification to active agents including minoxidil includes converting the active to a salt using either an acid such as lactic acid or converting it to a salt by using cyclodextrin. The fact that the converted salt is encapsulated in a liposome later is irrelevant since Weiner teaches the equivalency of modifying minoxidil to a more soluble form by reacting it with cyclodextrin or lactic acid. Applicant must compare the unexpectedness of using an acid versus cyclodextrin to overcome this rejection. Moreover, with regard to independent claim 112, the examiner points out that Weiner's lipid vesicle reads on the penetrating enhancer. Note US 20070092462, paragraph 0029 to substantiate the examiners' position that liposomes are known penetration enhancers.

Claims 14, 30-33, 36-44, and 133 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 97/03638 to Navarro et al in view of WO 97/12602 to Weiner et al in further view of Wong et al (5,130,142).

The teachings of Navarro and Weiner have been set forth above.

The references do not teach the elected glycerol cosolvent or a propellant.

Wong teaches a hair growth formulation. Wong teaches a composition in solution form can be applied to the skin as is, or else can be formulated into an aerosol and applied to the skin as a spray-on. To formulate an aerosol composition, a suitable propellant is used to expel the contents of the container. See column 9, lines 10-15 and column 12, lines 16-25. Further, Wong teaches solvents include glycerol, propylene alcohol, polyethylene glycol, butanediol are solvents. Other conventional ingredients include antioxidants.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of the above references and further utilize a propellant. One would have been motivated to do so if one desired administering the solution as a spray-on since Wong teaches a propellant allows a solution to aerosolize (expel from the container). Further, it would have been obvious to use either propylene glycol or glycerol and arrive at the instant invention. One would have been motivated to do so since Wong teaches both are solvents conventionally used in the art. Further, a skilled artisan would have expected similar results absent unexpected results since both are polyhydric alcohol. Further, the use of a conventional excipient such as an antioxidant is considered obvious if one desired to prevent oxidation.

Claims 112, 118-119, 121-128, 131-132, 135-138 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bazzano (5183817) in view of WO 97/12602 or Yu et al (EP0273202) respectively.

Bazzano teaches a minoxidil composition to increase growth rate and stimulate new hair growth by administering a lotion containing 0.01-0.1% retinoic acid, 0.5-5% minoxidil, ethanol, 5-50% propylene glycol, 0.1% BHT, and distilled water (up to 10%). Formulation example II contains 1% retinoic acid, 10% minoxidil, 4% cetyl alcohol, 4% ethanol, and up to 100% water. Bazzano teaches the use of pharmaceutically acceptable acid salt. See column 19, lines 1-25. Bazzano states that minoxidil or its derivatives and analogs that are described in US patents 5910928, 3637697, 3461461, 4139619, and 4596812 are incorporated into the reference. US

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patent 3,461,461 teaches the acid salt derivatives including lactic acid and other instantly claimed acids of minoxidil. Bazzano discloses that a major problem in influencing hair growth is obtaining good percutaneous absorption of the active compounds. The retinoid compounds cause excellent absorption of the hair follicles. See column 19, lines 35-40. The formulation can contain any pharmaceutically acceptable carrier, additive, or solubilizer.

Although Bazzano states that a minoxidil derivative/analog may be utilized, Bazzano does not explicitly teach the use of an acid addition.

WO teaches a topical composition for minoxidil and teaches minoxidil is not soluble in water, acetone, ethyl acetate and although the alcohol based solutions of minoxidil have only some penetration. See page 2. WO teaches modifying the solubility of the active in an aqueous solution by making it more hydrophilic without changing the active agent's therapeutic properties. The active agent that is more hydrophilic, has improved penetration through the hair follicle. WO teaches modifying by reacting it with an hydroxy organic acid such as lactic acid. See page 3 and 4.

Yu et al teach additives such as hydroxy acids enhance the therapeutic effects of pharmaceutical and cosmetic actives in topical treatments. See page 2. The pharmaceutical or cosmetic active is utilized generally in the amount of 0.01-40% and the hydroxyl acid is used in the amount of 0.01-99%. See page 6. Yu teaches the use of 3% lactic acid with minoxidil to help the minoxidil dissolve in the solution and enhance penetration and the efficacy of minoxidil on hair growth. The pH of the solution is 4.7. See example 3.

It is would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Bazzano and WO and utilize the instant minoxidil acid salt. One would have been motivated to do so since WO teaches this addition to yield a hydrophilic compound, allows for better penetration into the hair follicles. Further, since Bazzano is concerned with penetration of the composition into the hair follicle one would expect an additive effect of increasing penetration of the composition by adding instant salt. A skilled artisan would have reasonably expected success and similar results since Bazzano also teaches the acid salts may be utilized and incorporated other US patents wherein the instant acid salt is taught.

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Alternatively, it would have been obvious to one of ordinary skill in the art at the time the invention was made combine the teaching of Bazzano and Yu et al and utilize the instant acid. One would be motivated to do so Yu teaches adding lactic acid dissolves minoxidil providing better penetration of minoxidil. Therefore, a skilled artisan would have been motivated to add an acid for enhanced penetration of minoxidil into the hair follicle. Moreover, one would have expected similar results by the instant combination since Bazzano suggests the use of an acid addition salt.

With regard to the instantly claimed ratio, Bazzano sets forth a general range of components wherein water is utilized in an amount up to 10% and ethanol is to balance, thus it is within the skill of an artisan to look at the guidance provided by Bazzano and manipulate the concentrations (ratio) of water and ethanol depending on the concentration of the other components. It should be noted that generally difference in concentrations do not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such as concentration is critical. See *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Response to Arguments

Applicant argues that the instant claims language excludes retinoic acid since it affect the basic and novel characteristics of the composition. Applicant argues that Bazzano teaches retinoic acid is an essential ingredient in the formulation. Thus, applicant argues that a skilled artisan would not have been motivated to exclude Bazzano's retinoic acid.

Applicant's arguments filed 10/30/06 have been fully considered but they are not persuasive with regard to independent claim 112 and its depending claims. The examiner notes that the instant claim language excludes other active agents such as retinoic acid (the exclusion is supported by applicant's examples). However, claim 112 is directed to a composition that includes a penetration agent. The examiner points out that retinoic acid reads on a "penetrating agent". Note US 2003212077, paragraph 00014 to substantiate the examiner's position that retinoic acid is a known penetration enhancer.

Therefore, Bazzano renders the claims 112, 118-119, 121-128, 131-132, 135-138 obvious.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-4, 6, 8, 12-16, 19-21, 23-24, 26-33, 36-44, 112-114, 119-128, 131-133, and 135-138 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims of 21-24, 26-39 copending Application No. 10/949116. The examiner notes the Terminal Disclaimer filed on 10/30/06 over 10/949116; however the rejection is maintained until the Terminal Disclaimer is reviewed and accepted.

Although the conflicting claims are not identical, they are not patentably distinct from each other because:

Both instant application and copending application are directed to a composition consisting essentially of least 5% of a minoxidil, B) an acid selected from the group consisting of hydrochloric acid, sulphuric acid, nitric acid, and phosphoric acid, or an organic acid selected from the group consisting of citric acid, acetic acid, succinic acid, maleic acid, benzoic acid, lactic acid and mixtures thereof, C) a solvent selected from water and/or a lower alcohol, and D) a co-solvent selected from an aromatic or polyhydric alcohol in the amount of less than 10%, wherein the composition is in the form of a solution, tonic, ointment, mousse, a foam, shampoo, an aerosol, gel, paste, and cream.

It should be noted that the instant dependent claims and that of '116 have similar claims limitations.

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The difference between the instant claims and '116 is firstly that the instant claims are directed to compositions and the copending claims are directed to a method of using and preparing the composition. However, although '116 is not directed to a composition, one would necessarily have possession of the composition by practicing the method of '116.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

All the claims are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

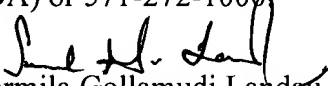
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila Gollamudi Landau whose telephone number is 571-272-0614. The examiner can normally be reached on M-F (8:00-5:30), alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Sharmila Gollamudi Landau
Primary Examiner
Art Unit 1616